REMARKS

Claims 39-53 and 59-63 are currently pending in the present application. Claims 1-38 and 54-58 have been canceled without prejudice or disclaimer thereto. Accordingly, claims 39-53 and 59-63 are currently under consideration.

35 U.S.C. §112, 2d

Claims 39, 43, 47, 49, 51 and 59 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed and reconsideration is respectfully solicited.

In the Office Action, it was asserted that the use of the terms "excipient" and "binder" render certain claims indefinite because the identity or the identities of the excipient and binder have not been provided in the remainder of the claim. It was also asserted that the term "at least" introduces an undefined upper limit which presumably makes the metes and bounds of the claim ill defined. Applicant respectfully traverses these assertions.

The threshold issue under 35 USC 112, second paragraph, is whether a person of ordinary skill in the art would have understood the metes and bounds of the claimed subject matter. See MPEP 2173. The term "excipient" and "binder" is unquestionably understood by those skilled in the art to which the application pertains. In fact, the references applied by the Examiner in the Office Action used these very terms. Hence, this is evidence that those of skill in the art understand the terms excipient and binder. Further, the Examiner's assertion that the term "at least" renders the claims indefinite because there is no upper limit is both factually unsupported and irrelevant to definiteness. The fact that the claims are open-ended and would read on additional elements is not a basis for lack of definiteness. If it were, than every open-ended claim would be indefinite. Applicant respectfully submits that the scope of the subject matter embraced by the claims is clear

and would be understood by those skilled in the art. This is evident from the references cited in this case. Nothing more is required for definiteness under the law. Accordingly, reconsideration and withdrawal of the rejection are respectfully solicited.

Double-Patenting

Claims 39-53 and 59-63 were rejected under the doctrine of obviousness-type double patenting over claims 1-17 of U.S. No. 6,720,000. The rejection is traversed. Nonetheless, Applicant respectfully requests that the rejection be held at abeyance until allowable subject matter is identified.

35 U.S.C. §103

Claims 39-53 and 59-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tam '097 in view of Liebowitz and further in view of Rudnic and Porter. The rejections are traversed and reconsideration is respectfully solicited.

Independent claims 39 and 59 are directed to a process of forming ribavirin particles; while independent claims 47, 49 and 51 relate to processes of forming ribavirin mixtures. The dependent claims further define the processes of the independent claims. In each of these claims, water is added or combined with ribavirin. None of the cited references suggest the processes of the instant claims.

Applicant respectfully submits that the claimed processes are patentable over the art cited by the Examiner. Specifically, the processes described by the instant claims are the opposite of that suggested by the art. Liebowitz recognizes many processing difficulties in preparing ribavirin compositions, including polymorphic conversion, flowability, uniformity, etc. (See,

e.g., column 1, lines 15-35). However, to solve these processing difficulties, Liebowitz teaches a process that explicitly excludes a wetting agent.

Conventional wisdom of preparing ribavirin formulations as described in Liebowitz (5,914,128) was to avoid processing steps that resulted in undesirable formation of ribavirin polymorphic forms. See Liebowitz at column 1, lines 31-35. In fact, Liebowitz reported that it was surprising to prepare a ribavirin formulation substantially free of polymorphic forms. See Liebowitz at column 3, lines 40-50. The conventional wisdom was that certain processing steps, including heat generated from a compaction step, would result in the formation of undesirable polymorphic forms of ribavirin. Id. Further, according to the Merck Index, ribavirin is a water soluble drug. Hence, those skilled in the art would have readily known that use of water in processing of ribavirin would not be desirable because of the potential for polymorphic conversion which was reported to be undesirable.

Accordingly, Liebowitz teaches a "dry" compaction process. (See, e.g., column 1, lines 30-34; column 1, line 52; column 4, beginning at line 65, the section titled "Manufacturing Procedure".) In many respects, the Liebowitz process is the opposite of the claimed process. There is no teaching or suggestion anywhere in Liebowitz relating to the use of adding water to a ribavirin mixture, as recited by claims 39-53 and 59-63.

Moreover, there is no teaching or suggestion in Liebowitz of a drying step, as recited by claims 47-53. The lack of this step is not surprising since Liebowitz never suggests wetting its mixture in the first instance.

As noted by the Examiner, Tam does not disclose, teach or suggest any process steps for the preparation of any pharmaceutical composition. Tam simply discloses that ribavirin compositions were known prior to Applicant's application.

Hence, the combination of Tam and Liebowitz would not motivate one skilled in the art at the time to arrive at the presently claimed subject matter. Tam has nothing to do with the preparation of ribavirin compositions and Liebowitz teaches process steps that are the opposite of the present process claims. Accordingly, it is respectfully submitted that the combination of Tam and Liebowitz not only fails to reach the presently claimed process but, in fact, teaches away from it.

The additional secondary references do not cure the deficiencies of Tam and Liebowitz. Rudnic relates to general production methods for preparing oral solid dosage forms and Porter teaches general techniques for applying coatings to solid dosage forms.

The secondary references teach dry and wet processes. They teach ingredients for fast dissolving and sustained release formulations. They teach nothing specifically regarding the preparation of a ribavirin composition and there is no reason why one of ordinary skill in the art at the time would pick and choose among the general teaching of these secondary references to arrive at the presently claimed subject matter.

Indeed, Liebowitz has already taught a process that allegedly solves many of the art recognized difficulties of preparing ribavirin solid dosage forms. Hence, those skilled in the art would be motivated to follow the dry compacting process of Liebowitz. Given the problems associated with ribavirin formulations, as identified by Liebowitz, it is respectfully submitted that one of skill in the art would not expect success in practicing the opposite of what Liebowitz teaches.

Hence, it is respectfully submitted that the combination of cited art, and art known as of the filing date of the present application, would not have lead one of skill in the art to a process

of preparing a ribavirin composition, with a likelihood of success, by adding a wetting agent or water thereto, as recited in claims 39-53 and 59-63.

Based on the forgoing, it is respectfully submitted that the claims in the application are patentable. Accordingly, reconsideration and allowance of the application are respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Daniel Bucca, Ph.D.
Registration No. 42,368

Please recognize our Customer No. 20277 as our correspondence address.

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 202.756.8000 DB:ajb
Facsimile: 202.756.8087
Date: 25 August 2008

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